DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS OR BECAUSE OF SUBSTITUTION[1]

156. Adulteration and misbranding of Elixir Sodium Salicylate Compound. U. S. v. Standard Pharmacal Co. Plea of nolo contendere. Fine, $25. (F. D. C. No. 956. Sample No. 55545–D.)

This product was represented to be a drug the name of which is recognized in the National Formulary. It contained potassium iodide in excess of the amount specified in the National Formulary, and in excess of the amount declared on its label.

On May 14, 1940, the United States attorney for the Northern District of Illinois filed an information against the Standard Pharmacal Co., a corporation, Chicago, Ill., alleging shipment by said company on or about July 31, 1939, from the State of Illinois into the State of Indiana, of a quantity of elixir sodium salicylate compound which was adulterated and misbranded.

Adulteration was alleged in that the article was represented as a drug the name of which is recognized in an official compendium, the National Formulary, and its strength differed from the standard set forth in said compendium in that 1,000 cubic centimeters of the article contained not less than 20.2 grams of potassium iodide, equivalent to 9.19 grains per fluid ounce; whereas the National Formulary provides that compound elixir of sodium salicylate shall contain in each 1,000 cubic centimeters 15 grams of potassium iodide, equivalent to 6.84 grains per fluid ounce and the difference in strength of the article from the said standard was not stated plainly on the label.

Misbranding was alleged in that the representation on the label that each fluid ounce represented 3¾ grains of potassium iodide was false and misleading since each fluid ounce of the article contained not less than 9.19 grains of potassium iodide.

On June 24, 1940, a plea of nolo contendere was entered on behalf of the defendant, and the court imposed a fine of $25.

157. Adulteration and misbranding of mineral oil. U. S. v. 1,149 Packages of Mineral Oil. Default decree of condemnation and destruction. (F. D. C. No. 1944. Sample No. 2344–E.)

This product failed to comply with the standard prescribed by the United States Pharmacopoeia since tests showed that it contained carbonizable substances; whereas the pharmacopoeia provides that white mineral oil shall be free from such substances.

On May 16, 1940, the United States attorney for the District of Massachusetts filed a libel against 1,149 packages of mineral oil at Springfield, Mass., alleging that the article had been shipped in interstate commerce on or about April 5, 1940, by the Tyler Products Co. from Pawtucket, R. I.; and charging that it was adulterated and misbranded. It was labeled in part: "Federal Mineral Oil * * * U. S. P. Standard."

Adulteration was alleged in that the article purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia and its quality or purity fell below the standard set forth in the pharmacopoeia and its difference from the standard was not plainly stated on the label.

It was alleged to be misbranded in that the representations in the label that it was mineral oil of United States Pharmacopoeial standard, was false and misleading since it did not comply with the tests laid down in the pharmacopoeia for mineral oil.

On June 24, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

158. Adulteration and misbranding of mineral oil. U. S. v. 117 Bottles of Russian Oil U. S. P. Mineral Oil. Default decree of condemnation and destruction. (F. D. C. No. 1779. Sample No. 2247–E.)

This product was light mineral oil and not heavy mineral oil as indicated by its labeling.

On April 11, 1940, the United States attorney for the District of Rhode Island filed a libel against 117 bottles of mineral oil at Providence, R. I., alleging that the article had been shipped in interstate commerce on or about February 20, 1940, by Diamond Drug & Magnesia Co., Boston, Mass.; and charging that it

[1] See also N. J. Nos. 146, 182, and 215.

was adulterated and misbranded. It was labeled in part: "Russian Oil U. S. P. Mineral Oil * * * General Drug & Oil Co., Inc., Boston, Mass."

It was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in an official compendium and its strength differed from, or its quality or purity fell below, the standard set forth in such compendium.

It was alleged to be misbranded in that the representations in the labeling that it was "Genuine Pure Russian Oil U. S. P. Mineral Oil" were false and misleading.

On May 2, 1940, no claimant having appeared, judgment of condemnation was entered and it was ordered that the product be destroyed.

159. Adulteration and misbranding of quinine sulfate. U. S. v. 132 Bottles of Quinine Sulfate. Default decree of condemnation and destruction. (F. D. C. No. 1313. Sample No. 84280–D.)

This product contained moisture in excess of the amount specified by the United States Pharmacopoeia. The containers were deceptive since their contents occupied only about 89 percent of the capacity of the bottles. Most of the bottles examined contained less than the amount indicated by the label.

On or about January 15, 1940, the United States attorney for the Western District of Arkansas filed a libel against 132 bottles of quinine sulfate at Fort Smith, Ark., alleging that the article had been shipped in interstate commerce on September 18, 1939, by the Frank Tea & Spice Distributing Co. from Cincinnati, Ohio; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia and its strength differed from and its quality fell below the standard set forth in the said pharmacopoeia since the moisture content was 8.9 percent; whereas the pharmacopoeia specifies that quinine sulfate shall contain not more than 5 percent moisture.

Misbranding was alleged in that representations appearing in the labeling that the article was U. S. P. X. quinine sulfate and contained about 15 percent water of crystallization and complied with tests laid down in the U. S. Pharmacopoeia for quinine sulfate, were false and misleading. The article was alleged to be misbranded further in that the statement "No. ⅛," borne on the wrapper and carton, meant that the bottles contained ⅛ ounce, and was false and misleading since it was incorrect. It was alleged to be misbranded further in that the containers were so made, formed, or filled as to be misleading.

On March 25, 1940, no claimant having appeared, judgment of condemnation was entered and it was ordered that the product be destroyed.

160. Adulteration and misbranding of peroxide of hydrogen. U. S. v. 708 Bottles of Peroxide of Hydrogen. Default decree of condemnation and destruction. (F. D. C. No. 838. Sample No. 74042–D.)

This product contained not more than 1.87 grams of H_2O_2 per 100 cc.; whereas the pharmacopoeia requires that solution of hydrogen peroxide shall contain not less than 2.5 grams of H_2O_2 per 100 cc. It contained about double the amount of preservative (in this case acetanilid) specified in the pharmacopoeia and about double the amount declared on the label. Its labeling bore false and misleading representations regarding its efficacy in the treatment of boils, sores, and abscesses.

On or about October 30, 1939, the United States attorney for the District of Connecticut filed a libel against 708 bottles of peroxide of hydrogen at New London, Conn., alleging that the article had been shipped in interstate commerce on or about September 28, 1939, by the Sunlight Chemical Corporation from Phillipsdale, R. I.; and charging that it was adulterated and misbranded.

Adulteration was alleged in that the article purported to be or was represented as a drug the name of which is recognized in the United States Pharmacopoeia, and its strength differed from and its quality and purity fell below the standard set forth therein for solution of hydrogen peroxide. It was alleged to be adulterated further in that its strength differed from and its quality fell below that which it purported or was represented to possess in that it was represented to contain 3 percent of H_2O_2 but contained a smaller amount.

It was alleged to be misbranded in that representations in the labeling that it contained 3/16 grain of acetanilid per fluid ounce and was efficacious in the treatment of boils, sores, and abscesses, were false and misleading since it contained slightly less than ½ grain of acetanilid per fluid ounce and was not a competent treatment for boils, sores, and abscesses.